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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,278	09/29/2003	David M. Goldenberg	40923-0134US1	8186

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,278	GOLDENBERG ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-106 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-106 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 in part, 3-52, 77, and 78, drawn to a monoclonal antibody that binds NCA90, classified in class 530, subclass 387.1.

II. Claims 1 in part, 2, 14-52, 77 and 78, drawn to a monoclonal antibody that binds NCA95, classified in class 530, subclass 387.1.

III. Claims 53, 54, 57, 58, 75, 76, and 81-106, drawn to a method of treating a malignancy, classified in class 424, subclass 178.1.

IV. Claims 55-58, 75, 76, and 81-106, drawn to a method of diagnosing or detecting a malignancy, classified in class 424, subclass 178.1.

V. Claims 59 in part, 60 and 61, drawn to a nucleic acid encoding an antibody that binds NCA90, vector and host cell, classified in class 536, subclass 23.53.

VI. Claims 59 in part, 60 and 61, drawn to a nucleic acid encoding an antibody that binds NCA95, vector and host cell, classified in class 536, subclass 23.53.

VII. Claims 62-64, drawn to a method of delivering an agent, classified in class 436, subclass 500, for example.

VIII. Claims 65-74, drawn to a method of diagnosing or detecting a malignancy in vitro, classified in class 435, subclass 7.1.

IX. Claim 79, drawn to a method of screening for a targetable conjugate, classified in class 435, subclass 7.1.

X. Claim 80, drawn to a method of imaging malignant or ischemic tissue or cells, classified in class 424, subclass 178.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group I can be used in both the method of treatment of Group III and the method of diagnosis of Group IV, or in a method of protein purification.

Inventions II and III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group II can be used in both the method of treatment of Group III and the method of diagnosis of Group IV, or in a method of protein purification.

Inventions of Groups I, II, V, and VI represent separate and distinct products which are made by materially different methods, and are used in materially different

methods which have different modes of operation, different functions and different effects. The polynucleic acids of Groups V and VI and the antibodies of Groups I and II are all structurally and chemically different from each other. The polynucleotides are made by nucleic acid synthesis, while antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening and the antibody can be used to immunopurify a polypeptide and the individual antibodies and nucleic acids have different structures and bind to different molecules. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II, V and VI are patentably distinct.

The methods of Inventions III, IV and VII-X differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites treatment of malignancy by administering an antibody; Invention IV recites diagnosis or detection of a malignancy; Invention VII recites delivering an agent; Invention VIII recites in vitro diagnosis or detection; Invention IX recites screening for a binding agent and Invention X recites imaging malignant or ischemic tissues or cells. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III, IV and VII-X are separate and distinct in having different method steps and different endpoints and are patentably distinct.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species. If Group I or II is elected, then an election of species is necessary between the following different drugs:

Species A: antimitotic

Species B: alkylating

Species C: antimetabolite

Species D: angiogenesis-inhibiting agents

Species E: apoptotic

Species F: alkaloid

Species G: COX-2 inhibiting agents

Species H: antibiotic agents

Species I: nitrogen mustards

Species J: ethylenimine derivatives

Species K: alkyl sulfonates

Species L: nitrosoureas

Species M: triazenes

Species N: folic acid analogs

Species O: anthracyclines

Species P: taxanes

Species Q: pyrimidine analogs

Species R: purine analogs

Species S: enzymes

Species T: epipodophyllotoxins

Species U: platinum coordination complexes

Species V: vinca alkaloids

Species W: substituted ureas

Species X: methyl hydrazine derivatives

Species Y: adrenocortical suppressants

Species Z: hormone antagonists

Species AA: enzyme inhibitors

Species AB: endostatin

Species AC: taxols

Species AD: other taxanes

Species AE: camptothecins

Species AF: doxorubicins and their analogs

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

If Group I or II is elected, then an election of species is necessary between the following different toxins:

Species BA: plant

Species BB: microbial

Species BC: animal

Species BD: ricin

Species BE: abrin

Species BF: alpha toxin

Species BG: saporin

Species BH: ribonuclease (RNase)

Species BI: DNase 1

Species BJ: Staphylococcal enterotoxin-A

Species BK: pokeweed antiviral protein

Species BL: gelonin

Species BM: diphtherin toxin

Species BN: Pseudomonas exotoxin

Species BO: Pseudomonas endotoxin

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

If any of Groups I, II, or X are elected, then an election of species is necessary between the following different targetable conjugate molecules:

Species CA: DOTA-Phe-Lys(HSG)-D-Tyr-Lys(HSG)-NH2

Species CB: DOTA-Phe-Lys(HSG)--Tyr-Lys(HSG)-NH2(SEQ ID NO: 7)

Species CC: Ac-Lys(HSG)D-Tyr-Lys(HSG)-Lys(Tscg-Cys)-NH2

Species CD: DOTA-D-Asp-D-Lys(HSG)-D-Asp-D-Lys(HSG)- NH2

Species CE: DOTA-D-Glu-D-Lys(HSG)-D-Glu-D-Lys(HSG)-NH2

Species CF: DOTA-D-Tyr-D-Lys(HSG)-D-Glu-D-Lys(HSG)-NH2

Species CG: DOTA-D-Ala-D-Lys(HSG)-D-Glu-D-Lys(HSG)-N H2

Species CH: DOTA-D-Phe-D-Lys(HSG)-D-Tyr-D-Lys(HSG)-NHz

Species CI: Ac-D-Phe-D-Lys(DOTA)-D-Tyr-D-Lys(DOTA)-N H2

Species CJ: Ac-D-Phe-D-Lys(DTPA)-D-Tyr-D-Lys(DTPA)-N H2

Species CK: Ac-D-Phe-D-Lys(Bz-DTPA)-D-Tyr-D-Lys(Bz-DTPA)-N H2

Species CL: Ac-D-Lys(HSG)-D-Tyr-D-Lys(HSG)-D-Lys(Tscg-Cys)-N H2

Species CM: DOTA-D-Phe-D-Lys(HSG)-D-Tyr-D-Lys(HSG)-D-Lys(Tscg-Cys)-N Hz

Species CN: (Tscg-Cys)-D-Phe-D-Lys(HSG)-D-Tyr-D-Lys(HSG)-D-Lys(DOTA)-NH2

Species CO: Tscg-D-Cys-D-Glu-D-Lys(HSG)-D-Glu-D-Lys(HSG)-NH2

Species CP: (Tscg-Cys)-D-Glu-D-Lys(HSG)-D-Glu-D-Lys(HSG)-N H2

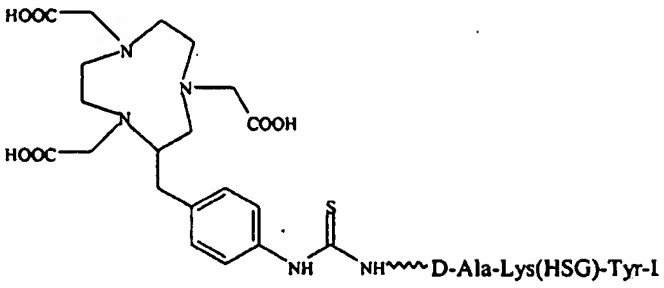
Species CQ: Ac-D-Cys-D-Lys(DOTA)-D-Tyr-D-Ala-D-Lys(DOTA)-D-Cys-NH2

Species CR: Ac-D-Cys-D-Lys(DTPA)-D-Tyr-D-Lys(DTPA)-NH2

Species CS: Ac-D-Lys(DTPA)-D-Tyr-D-Lys(DTPA)-D-Lys(TscG-Cys)-N H2

Species CT: Ac-D-Lys(DOTA)-D-Tyr-D-Lys(DOTA)-D-Lys(TscG-Cys)-N H2

Species CU:



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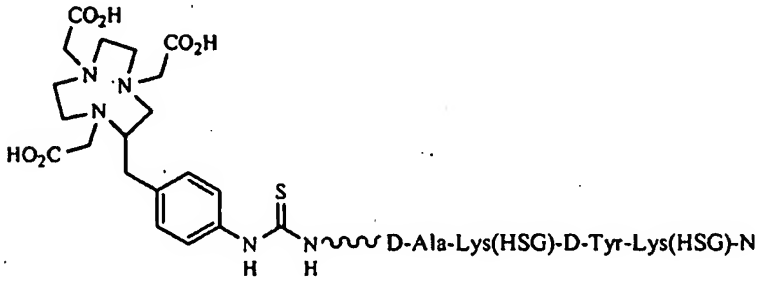

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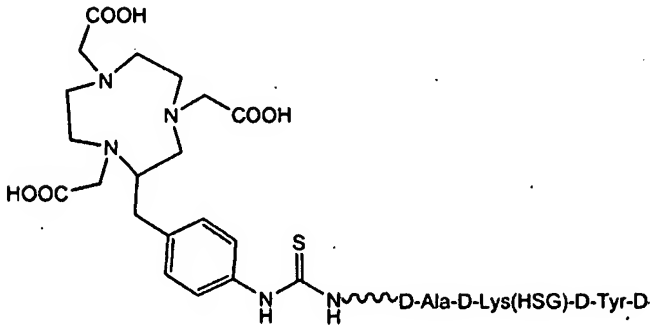

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-30, 35-74, 77, 79, 81-generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the

election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 19, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER